

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Letters Patent of:
Rosen et al.

Docket No.: PF596P1N

U.S. Patent No.: 7,601,351

Issued: October 13, 2009

For: ANTIBODIES AGAINST PROTECTIVE
ANTIGEN

**REQUEST FOR RECONSIDERATION OF DECISION ON APPLICATION FOR
PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(b) AND
APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d)**

MS Petitions
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Request for Reconsideration of Decision on PTA Application Under 37 C.F.R. § 1.705(b)

Patentees respectfully request reconsideration of the Decision on Application for Patent Term Adjustment mailed September 14, 2009 (the “Decision”). Patentees disagree with the Decision, and maintain that, as set forth in Patentees’ Application for Patent Term Adjustment under 37 C.F.R. § 1.705(b) filed March 6, 2009 (the “PTA Application Under 1.705(b)”), Application No. 10/602,727, now U.S. Patent No. 7,601,351 (the “351 Patent”) was entitled to an initial determination of 594 days of PTA, rather than the 400 days indicated in the Determination of Patent Term Adjustment under 35 U.S.C. 154(b) mailed on December 10, 2008.

Moreover, although the Decision addressed the merits of the PTA Application Under 1.705(b) and did not question that the applicable procedural requirements had been met, the Office dismissed rather than denied the PTA Application Under 1.705(b). The Office has asserted in M.P.E.P. § 1002.02 that dismissal of a request under 37 C.F.R. § 1.705 is not a final agency decision, but that denial of such a request is a final agency decision. It is unclear to Patentees whether the Office’s position is that a patentee is required to obtain a final agency decision on a request for reconsideration under 35 U.S.C. § 154(b)(3) in order to exhaust his or her administrative remedies prior to obtaining relief in an appeal under 35

U.S.C. § 154(b)(4), or whether such an appeal is independent of any request under 35 U.S.C. § 154(b)(3) and a final agency decision thereon. Thus, Patentees respectfully request reconsideration of the Decision and ask that the Office (a) issue a final agency decision granting the PTA Application Under 1.705(b), (b) issue a final agency decision denying the PTA Application Under 1.705(b), or (c) confirm that the Office does not contend that a final agency decision on a request for reconsideration under 35 U.S.C. § 154(b)(3) is required in order to obtain relief in an appeal under 35 U.S.C. § 154(b)(4).

Application for Patent Term Adjustment Under 37 C.F.R. § 1.705(d)

Additionally, Patentees hereby request reconsideration of the Patent Term Adjustment (PTA) indicated on the face of the '351 Patent (983 days). Patentees believe the correct PTA is 1,546 days taking into account the interpretation of 35 U.S.C. § 154 articulated in the controlling U.S. District Court for the District of Columbia in *Wyeth v. Dudas*, 580 F. Supp. 2d 138 (D.D.C. 2008) ("*Wyeth*") and the PTA due pursuant to the PTA Application Under 1.705(b) discussed above.

This request under 37 C.F.R. § 1.705(d) is being timely made, as it is submitted within two months of the issuance of the patent, and could not have been made in an application for PTA under 37 C.F.R. § 1.705(b) because the request pertains to the issue date of the captioned patent and the appropriate PTA due under 35 U.S.C. § 154(b)(1)(B). The requirements of 37 C.F.R. § 1.705(b)(1) are satisfied by the electronic fee transmittal submitted herewith, authorizing payment of the fee set forth in 37 C.F.R. § 1.18(e). The requirements of 37 C.F.R. § 1.705(b)(2) are satisfied by the following Statement of Facts.

STATEMENT OF FACTS

1. The application was filed on June 25, 2003, and is thus eligible for PTA under 35 U.S.C. § 154.
2. The instant application is not subject to a terminal disclaimer.
3. A Notice to File Missing Parts was mailed October 9, 2003. Patentees timely responded on December 9, 2003.

4. Although the instant application was filed on June 25, 2003, the Office failed to initially act on the application within the 14 month permitted time frame allowed under 35 U.S.C. § 154(b)(1)(A)(i). In particular, an office action was not mailed until March 7, 2006. Thus, Patentees are entitled to a PTA of 559 days due to the Patent Office's delay from the day after the date fourteen months after the application was filed (August 26, 2004) to the date of mailing of the first notification under 35 U.S.C. 132 (March 7, 2006). *See* 35 U.S.C. § 154(b)(1)(A)(i) and 37 C.F.R. §§ 1.702(a)(1) & 1.703(a)(1).
5. A complete reply to the March 7, 2006 office action was filed on July 7, 2006 with a petition for an extension of time of three months. Pursuant to 37 C.F.R. § 1.704, this filing incurred a PTA reduction of 30 days from the day after the date three months after the mailing of the office action (June 8, 2006) to the date of the response (July 7, 2006).
6. An Information Disclosure Statement (IDS) was filed on July 11, 2006. According to the PAIR system, a PTA reduction of 4 days was applied as a result of this filing. *See* PAIR Patent Term Adjustment History (Exhibit A). For the reasons discussed in the PTA Application Under 1.705(b), Patentees do not believe that this PTA reduction is appropriate.
7. A Notice to Comply requesting a new Sequence Listing was mailed on October 13, 2006. For the reasons discussed in the PTA Application Under 1.705(b), Patentees disagree that this Notice was a proper response under 35 U.S.C. § 132 in compliance with 35 U.S.C. § 154(b)(1)(A)(ii) and 37 C.F.R. §§ 1.702(a)(2) & 1.703(a)(2) to Patentees' July 7, 2006 reply.
8. A response to the Notice to Comply was filed on January 16, 2007, with a petition for an extension of time of two months. Pursuant to 37 C.F.R. § 1.704, this filing incurred a PTA reduction of 3 days from the day after the date three months after the mailing of the Notice (January 14, 2007) to the date of the response (January 16, 2007).

9. A non-final office action responsive to Patentees' July 7, 2006 reply was mailed on July 19, 2007. For the reasons discussed in the PTA Application Under 1.705(b), Patentees believe that the Office failed to respond under 35 U.S.C. § 154(b)(1)(A)(ii) within the 4 month permitted time frame after Patentees' July 7, 2006 reply. Thus, Patentees are entitled to a PTA of 254 days due to the Patent Office's delay from the day after the date four months after date the reply was filed (November 8, 2006) and ending on the date of mailing of the non-final office action under 35 U.S.C. 132 (July 19, 2007). *See* 37 C.F.R. §§ 1.702(a)(2) & 1.703(a)(2).
10. A response to the July 19, 2007 non-final office action was filed on January 22, 2008 with a petition for an extension of time of three months. Pursuant to 37 C.F.R. § 1.704, this filing incurred a PTA reduction of 95 days from the day after the date three months after the mailing of the office action (October 20, 2007) to the date of the response (January 22, 2008).
11. A final office action was mailed on April 28, 2008.
12. A response to the final office action was filed on October 27, 2008 with a petition for an extension of time of three months. Pursuant to 37 C.F.R. § 1.704, this filing incurred a PTA reduction of 91 days from the day after the date three months after the mailing of the office action (July 29, 2008) to the date of the response (October 27, 2008).
13. On December 10, 2008, a Notice of Allowance was mailed. Together with the Notice of Allowance, a Determination of Patent Term Adjustment (Form PTOL-85) under 35 U.S.C. § 154(b) was mailed indicating a PTA of 400 days.
14. The issue fee transmittal form was filed, and the issue fee was timely paid, on March 6, 2009.

15. The PTA Application Under 1.705(b) was filed on March 6, 2009.
16. The Decision was mailed September 14, 2009, indicating that the PTA Application Under 1.705(b) was dismissed.
17. The '351 Patent was issued on October 13, 2009. Accordingly, the Office failed to issue the '351 Patent within four months of the payment of the issue fee pursuant to 35 U.S.C. § 154(b)(1)(A)(iv). Thus, Patentees are entitled to a PTA of 99 days due to the Patent Office's delay from the day after the date four months after the issue fee was paid (March 7, 2009) to the date of issuance of the '351 Patent (October 13, 2009). *See* 35 U.S.C. § 154(b)(1)(A)(iv) and 37 C.F.R. §§ 1.702(a)(4) & 1.703(a)(6).
18. The Office also failed to issue the '351 Patent within three years of its actual filing date pursuant to 35 U.S.C. § 154(b)(1)(B). Thus, Patentees are entitled to PTA of 1,206 days due to the Patent Office's delay from the day after the date three years after the application was filed (June 26, 2006) to the date that the patent was issued (October 13, 2009), to the extent that such delay does not overlap with other periods of delay. *See* 35 U.S.C. §§ 154(b)(1)(B) and 154(b)(2) and 37 C.F.R. § 1.703(b).
19. Other than the circumstances described above, there have been no circumstances that could reasonably be construed as a failure to engage in reasonable efforts to conclude processing or examination of this application.
20. On September 30, 2008, the U.S. District Court for the District of Columbia decided *Wyeth v. Dudas*, 580 F. Supp. 2d 138 (D.D.C. 2008). In *Wyeth*, the District Court disagreed with the PTO's interpretation that the entire period during which an application is pending before the PTO (excluding the periods of 35 U.S.C. § 154(b)(1)(B)(i)-(iii)) is the relevant period for determining whether periods of delay under 35 U.S.C. § 154(b)(1)(B) (37 C.F.R. §§ 1.702(b) and 1.703(b)) overlap with periods of delay under 35 U.S.C. § 154(b)(1)(A) (37 C.F.R. §§ 1.702(a) and 1.703(a)). Specifically, the District Court disagreed with the PTO's interpretation

because it considers an application as delayed under 35 U.S.C. § 154(b)(1)(B) during the period before it has been delayed under the three-year pendency provision. In addition, the District Court found the language in 35 U.S.C. § 154(b)(2)(A) and 37 C.F.R. § 1.703(f) regarding the overlap of the periods was not ambiguous and indicated that delays under 35 U.S.C. § 154(b)(1)(B) (“B delays” in *Wyeth*) begin “when the PTO has failed to issue a patent within three years, not before.” *Wyeth* is controlling authority with respect to the interpretation of 35 U.S.C. § 154(b)(2)(A) by the Office.

ARGUMENT

As noted above and in the PTA Application Under 1.705(b), reconsideration of which has been requested herein, Patentees disagree with the Office’s calculation of PTA in the December 10, 2008 Determination of Patent Term Adjustment under 35 U.S.C. § 154(b). Taking into account the PTA requested by Applicants in the PTA Application Under 1.705(b) and the 99 days of PTA accorded by the Office for failure to issue the instant patent within four months of the payment of the issue fee as discussed above, the ‘351 Patent is entitled to a PTA under 35 U.S.C. § 154(b)(1)(A) of 912 days, less a PTA reduction under 37 C.F.R. § 1.704 of 219 days, plus any PTA for the delayed issuance of the patent pursuant to 35 U.S.C. § 154(b)(1)(B) to the extent that such delay does not overlap with the delay under 35 U.S.C. § 154(b)(1)(A). Leaving aside the issues addressed in the PTA Application Under 1.705(b), the ‘351 Patent is at least entitled to a PTA under 35 U.S.C. § 154(b)(1)(A) of 722 days, less a PTA reduction under 37 C.F.R. § 1.704 of 223 days, plus any PTA for the delayed issuance of the patent pursuant to 35 U.S.C. § 154(b)(1)(B) to the extent that such delay does not overlap with the delay under 35 U.S.C. § 154(b)(1)(A).

Based on the PTA noted on the face of the ‘351 Patent and the PAIR record, the Office accorded the ‘351 Patent with 484 days of PTA for the delayed issuance of the patent pursuant to 35 U.S.C. § 154(b)(1)(B), presumably based on an implicit finding that the 1,206 day delay under 35 U.S.C. § 154(b)(1)(B) overlapped with the entire delay under 35 U.S.C. § 154(b)(1)(A). However, in view of the *Wyeth* decision, it is clear that delays under 35 U.S.C. § 154(b)(1)(B) (and therefore under 37 C.F.R. §§ 1.702(b) and 1.703(b)) do not begin until the PTO has failed to issue a patent within three years, subject to the exclusions of 35 U.S.C. § 154(b)(1)(B)(i)-(iii). In the instant case, the period of adjustment under 37 C.F.R. § 1.703(a), ending with the March 7, 2006 mailing of an office action, clearly does

not overlap with the period of adjustment under 37 C.F.R. § 1.703(b), beginning on June 26, 2006. Accordingly, Patentees are entitled to the period of adjustment under both 37 C.F.R. § 1.703(a)(1) and 37 C.F.R. § 1.703(b), rather than only the larger period under 37 C.F.R. § 1.703(b) as currently calculated. As such, Patentees are entitled to the full 1,206 days of PTA for the period of delay under 37 C.F.R. § 1.703(b), rather than 484 days as currently calculated, in addition to the 559 days of PTA for the period of delay under 37 C.F.R. § 1.703(a). Taking into account the PTA reduction under 37 C.F.R. § 1.704 of either 219 days or 223 days (depending on whether the PTA Application Under 1.705(b) is granted or denied), the total correct PTA for U.S. Patent No. 7,601,351 is either 1,546 days or 1,542 days.

To the extent that the Office intends to rely upon its interpretation of 35 U.S.C. § 154(b)(2)(A) as reflected in *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, 69 Fed. Reg. 34283 (June 21, 2004), Patentees note that *Wyeth* is a controlling decision of the U.S. District Court for the District of Columbia under 35 U.S.C. § 154(b)(4) which expressly ruled that the Office's interpretation of 35 U.S.C. § 154(b)(2)(A) was incorrect. While Patentees acknowledge that the Office has appealed *Wyeth* to the Federal Circuit and that the appeal has not yet been finally decided, the Office is required to follow the *Wyeth* decision absent a stay.

Thus, should the Office intend to act upon the instant application for patent term adjustment under 37 C.F.R. § 1.705(d) contrary to the *Wyeth* decision, Patentees request that the instant application be held in abeyance pending resolution of the *Wyeth* appeal. Such an action is clearly within the supervisory authority of the Director, and Patentees submit that the instant situation is the sort of extraordinary situation when justice requires relief. *See* 37 C.F.R. § 1.183. Indeed, Patentees respectfully assert that the Office's failure to either hold the instant application for PTA in abeyance pending resolution of the *Wyeth* appeal or to decide the instant application for patent term adjustment consistent with the interpretation of 35 U.S.C. § 154(b)(2)(A) held to be correct in *Wyeth* is improper and not in accordance with law (and may be arbitrary and capricious). This is particularly true as Patentees (and other patentees) are left with a Hobson's choice of either foregoing valuable PTA to which they may be entitled or incurring the substantial expense and effort of filing district court actions under 35 U.S.C. § 154(b)(4)(A) that will be made irrelevant by the final resolution of the *Wyeth* appeal. Indeed, Patentees understand that the U.S. District Court for the District of

Columbia is staying actions under 35 U.S.C. § 154(b)(4)(A) during the pendency of the *Wyeth* appeal. The Office should likewise hold applications for PTA based on the holding of *Wyeth* (or requests for reconsideration of such applications) in abeyance pending resolution of the *Wyeth* appeal. Should a petition under 37 C.F.R. §§ 1.181 to 1.183 be deemed necessary to grant a request for the instant application for PTA under 37 C.F.R. § 1.705(d) to be held in abeyance pending resolution of the *Wyeth* appeal, please treat the instant request as such a petition and charge any fee deemed to be required to Deposit Account No. 08-3425. In the event that the Office does not intend to hold the instant application for PTA under 37 C.F.R. § 1.705(d) in abeyance pending resolution of the *Wyeth* appeal, for the reasons discussed above in the Request for Reconsideration of Decision, Patentees respectfully request that the Office either (a) issue a final agency decision regarding the instant application for PTA under 1.705(d), or (b) confirm that the Office does not contend that a final agency decision on a request for reconsideration under 35 U.S.C. § 154(b)(3) is required in order to obtain relief in an appeal under 35 U.S.C. § 154(b)(4).

CONCLUSION

Accordingly, Applicants respectfully request that the PTA for the instant application be reconsidered and corrected, and/or that the requests made above be granted, in light of the facts and arguments presented herein. If any further information is required, please contact the undersigned at the number listed below. Please charge any additional fees due in connection with the filing of this paper, or credit any overpayment, to Deposit Account No. 08-3425.

Dated: November 13, 2009

Respectfully submitted,

/Mark J. Hyman/
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